

TFPI



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Chen and Hora

Serial No. 10/753,079

Filed: January 8, 2004

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Group Art Unit: 1643

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Examiner: SZPERKA, Michael Edward

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Atty. Dkt. No. 012441.00052
PP-18459.005

**For: STABILIZED LYOPHILIZED COMPOSITIONS COMPRISING TISSUE
FACTOR PATHWAY INHIBITOR OR TISSUE FACTOR PATHWAY
INHIBITOR VARIANTS**

RESPONSE TO RESTRICTION REQUIREMENT

U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This paper responds to the Office Action mailed March 15, 2005, which requires Applicants to elect claims reciting either TFPI or a TFPI variant for examination in this application. We believe no fee is due in connection with this filing. If a fee is required, please charge our Deposit Account No. 19-0733.

Applicants provisionally elect a TFPI variant and the disclosed species ala-TFPI with
traverse. Claims 1-21 read on the provisionally elected species.

The Manual of Patent Examining Procedure sets forth two criteria that must be met to make a proper restriction requirement. First, as stated in 35 U.S.C. § 121, the inventions must be independent or distinct. Second, there must be a “serious burden” on the examiner to justify the restriction. M.P.E.P. § 803 (8th ed., rev. May 2004). The M.P.E.P. further states that a serious burden may be *prima facie* shown “if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 802.02.” On the other hand, “[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.” M.P.E.P. § 803.

In this case, the Office Action has not provided the required *prima facie* showing of a serious burden. The Office Action contends that TFPI and TFPI variants are patentably distinct species “because their differing structures give rise to distinct physicochemical properties.” Office Action at page 2, second paragraph. But the Office Action provides no indication that TFPI and TFPI variants (or any of the disclosed species of TFPI variants) would be separately classified or searched in different fields. In this circumstance, the M.P.E.P. § 802.02 instructs that the claims should not be restricted:

[w]here, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions.

The specification teaches similarities in structure between TFPI and TFPI variants (par. [038]-[040]), biological activity (par. [043]), and therapeutic utility (par. [04]). Far from imposing a serious burden on the Examiner, it would be relatively easy for all the species disclosed in this application to be examined together.

Applicants request that the restriction requirement be withdrawn.

Respectfully submitted,

Dated: March 30, 2005

By:

A handwritten signature in black ink, appearing to read "Lisa M. Hemmendinger", written over a horizontal line.

Lisa M. Hemmendinger
Registration No. 42,653

Customer No. 22907